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Pinloc or Hansson pins: a multicenter, randomized controlled study of 439 patients treated for femoral neck fractures

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Abstract

Objectives: To compare the recently developed Hansson Pinloc system, which features 3 cylindrical parallel pins with hooks connected through a fixed-angle interlocking plate, with the Hansson Pin System (2 hook pins) for the treatment of femoral neck fractures.

Design: One hundred fourteen patients with displaced femoral neck fractures and 325 patients with nondisplaced fractures from 9 orthopaedic centers were randomized to either Hansson Pinloc system or Hansson Pin System and followed for 2 years or until death. Age at inclusion was 50 years or older.

Main Outcome Measurements: The primary outcome was failure (defined as early displacement, nonunion, symptomatic avascular necrosis, or deep infection). Secondary outcomes included revision surgery, Timed Up and Go (TUG) test and patient-reported outcome measures (PROMs: EQ-5D and WOMAC).

Results: For nondisplaced fractures, the incidence of failure was 14% (23/169) in the Pinloc group and 16% (25/156) in the Hansson group. For displaced fractures, the analysis was stratified by age. Patients aged 50–69 years with displaced fractures showed a 2-year failure rate of 44% (17/39) in the Pinloc group versus 44% (16/36) in the Hansson group. For patients 70 years or older with displaced fractures, 33% (7/21) in the Pinloc group versus 22% (4/18) in the Hansson group failed. At 3 and 12 months, no clinically significant differences between treatment groups were found for EQ-5D-3L, WOMAC, or for the TUG in any fracture type or age group.

Conclusions: There were no advantages for Pinloc in any of the studies aspects.

Level of evidence: 1

Key Words: femoral neck fracture, internal fixation, Hansson Pinloc system, Hansson Pin System

1. Introduction

During the last 25 years, several prospective randomized studies have shown that cemented arthroplasty is the treatment of choice for displaced femoral neck fractures (FNFs), with long-term follow-ups showing good results.[1–3] However, there are 2 categories of patients where internal fixation is often preferred, young patients and the frailest of the elderly. Unfortunately, failure rates of 20%–40% are reported after internal fixation of displaced FNFs.[4,5] Numerous implants have been designed and studied, e.g. screws, pins, sliding hip screws, and headless compression screws, without any one implant demonstrating superiority.[6,7]

By contrast, internal fixation is the treatment of choice for nondisplaced fractures. The failure rate, comprising avascular necrosis and nonunion, is around 5%–11%.[8] Even so, reports indicate that many patients without an obvious fracture failure are discontent.[9] Rogmark reported that 40% of all patients had hip pain when walking; this number was 51% among those younger than 80 years.[8]

The Hansson Pinloc system is a new implant featuring 3 cylindrical parallel pins with hooks, connected through a fixed angle interlocking plate (Swemac Innovations AB, Linköping, Sweden). Because the locking plate is not fixed to the femoral cortex, compression of the fracture along the femoral neck is allowed. Biomechanical laboratory studies have shown increased stability with Pinloc fixation, compared with 2 Hansson pins or cannulated screws.[10–12] To investigate whether these potentially advantageous biomechanical characteristics could improve patient outcome, we performed a randomized controlled study comparing Pinloc with Hansson pins. The primary outcome was failure within 2 years of the procedure. Secondary outcomes were revision surgery within 2 years and EuroQol-5 dimension-3 level (EQ-5D), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Timed Up and Go test (TUG) at 3 months and 1 year.

The authors have no conflicts of interest to disclose.

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We previously reported a 1-year interim analysis of failure and reoperation.[13] In this article, the completed study outcome including 2-year failure rates and patient-reported outcome measures (PROMs) are presented.

2. Patients and Methods

The study was designed as a prospective randomized controlled study. Nine orthopaedic centers across Sweden included patients in the trial between May 7, 2014, and February 25, 2017.

2.1. Patients

All patients 50 years or older, with an FNF suitable for treatment with internal fixation, at any of the study sites during the study period were potential study participants (Fig. 1). If the treating surgeon was comfortable with performing surgery with both study implants, the patient was asked to participate. Patients were excluded if the fracture was pathologic, if previously included in the study for a fracture of the contralateral hip, or if the patient declined participation.

2.2. Randomization

All patients were positioned on a fracture table. Closed reduction was performed if deemed necessary by the surgeon, and patients were then randomized to either Hansson Pinloc (Fig. 2) or Hansson Pin System (Swemac Innovations AB, Linköping, Sweden). All procedures were performed by consultants or trainees with a consultant supervising. An online randomization platform was used, and subjects were stratified according to site, displacement (nondisplaced/displaced), and age (50–69 or 70 and older). Allocation to treatment was made in blocks of 2, 4, or 6 in a random sequence.

The modified Garden classification was used by the treating surgeon to determine displacement (1–2 nondisplaced, 3–4 displaced).

2.3. Follow-up

The study subjects were followed for 2 years or until death if it occurred within 2 years. Outpatient follow-up was scheduled for 3 months and 1 year. At these time points, x-rays of the treated hip, patient-reported outcome measures (PROMs), and TUG were acquired. Two years postoperatively, medical records were scanned for failures and reoperations. In cases where new x-ray scans were available, these were also inspected for signs of failure.

2.4. Outcome Measures

The primary outcome was fracture failure, defined as early displacement, nonunion, symptomatic avascular necrosis, or deep infection within 2 years.

Secondary outcomes were revision surgery (performed or decided on within 2 years), PROMs, and TUG at 1 year. Revision surgery was defined as any surgery on the affected hip within 2 years. Implant removal due to local pain was reported separately because it was considered a less serious complication.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and EQ-5D were chosen as PROMs. WOMAC measures hip symptoms and function, and EQ-5D is a standardized measure of health-related quality of life.

The TUG test was performed at the 3-month and 12-month follow-ups. In this test, the subject is placed in a chair. On command, she/he stands up, walks 3 meters, walks back to the chair, and sits down. The time from the initial command to sitting down again is measured in seconds. In our case, the better of 2 attempts was recorded.[14]

2.5. Statistics

Failures, reoperations, and deaths were compared using the Chi-square and Fisher exact test for proportions. PROMs and TUG were compared using the Mann–Whitney U test. *P*-values <0.05 were considered statistically significant. A difference of 0.08 in

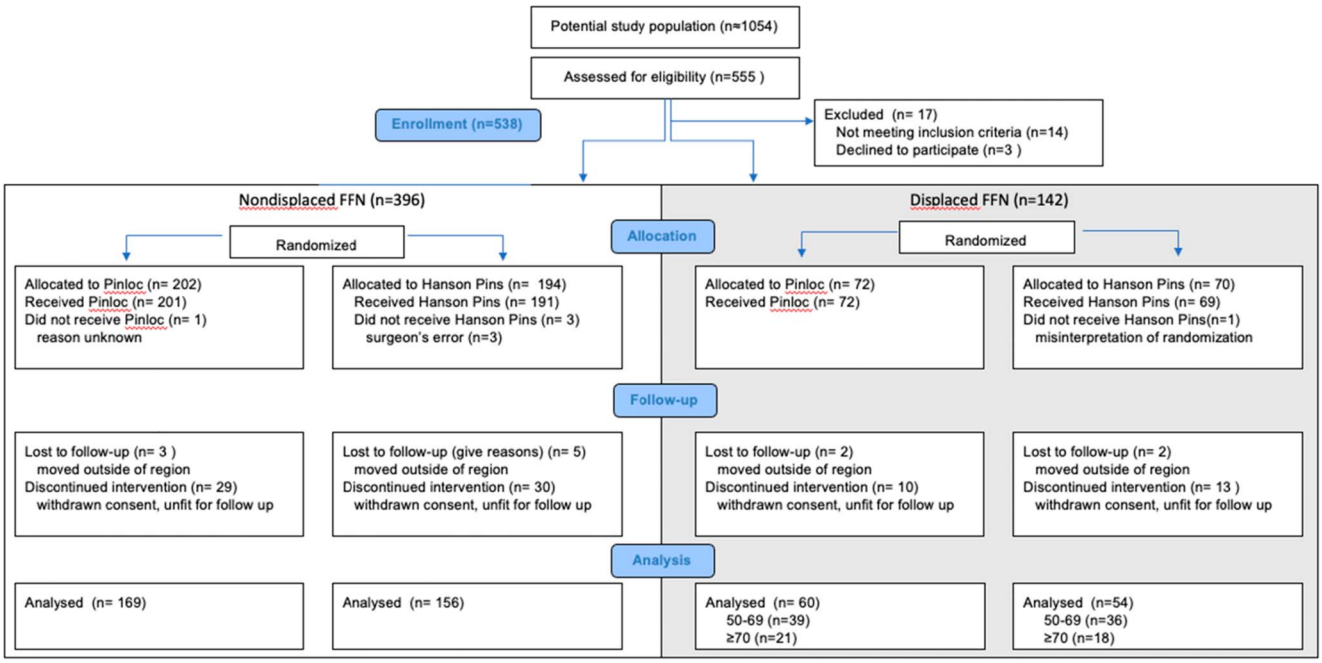

Figure 1. CONSORT flow diagram. All fractures. n: number.

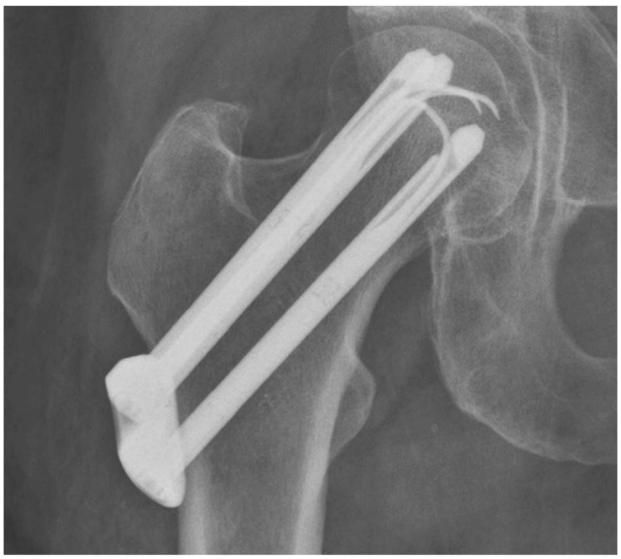

Figure 2. Hansson Pinloc. The construct consists of 3 hook pins with angular stable locking into a lateral plate.

the EQ-5D index score,[15,16] 10 in the VAS score, 10 in the WOMAC score,[17] and 4 seconds in the TUG test was considered clinically significant.[18] The results were not normally distributed according to the Kolmogorov–Smirnov test; hence, median and range are reported. Deceased persons were included in the study analysis up until death.

Power analyses were performed to determine group sizes. With an assumed reduction of failure rate from 40% to 20% in displaced fractures, 64 patients per group were needed to reach a power of 80%. With an assumed reduction of the TUG test result from 20 to 15 seconds in nondisplaced fractures, 110 patients per treatment group were needed to reach a power of 90%. A mortality rate of 30% within the first postoperative year was expected in the elderly patients.

2.6. Ethics, Registration, and Funding

The Regional Ethics Committee in Linköping approved the study on 2013-11-25 (2013/327-31). The study was registered at ClinicalTrials.gov (NCT02776631) and complies with the WMA Declaration of Helsinki. All subjects, or next of kin if unable, consented to participate after they were given verbal and written information before entering the study. Participating hospitals provided the necessary funding for the trial. No funding or financial support was received from Swemac Innovations AB, Linköping, Sweden. The participating surgeons report no conflicts of interest. Study subjects did not receive any financial support or compensation for their participation.

3. Results

3.1. Study Population

During the study period, 1054 patients were treated with internal fixation for a FNF at the participating clinics. Owing to variability in how these data were registered at different institutions, this number gives a rough estimate of the number of patients that could have been screened for eligibility (Fig. 1).

Five hundred and fifty-five patients were assessed for eligibility. Fourteen patients did not meet the inclusion criteria, and 3 patients declined to participate preoperatively (Fig. 1). Thus, our study population consisted of 538 patients. Of these, 396 patients had nondisplaced fractures and 142 had a displaced fracture.

3.2. Nondisplaced Fractures

Three hundred and ninety-six patients with nondisplaced fractures were randomized, and it was possible to include 325 for analysis in the study (Fig. 1). Patient demographics with regard to sex, age, BMI, dementia, and smoking were similar in both treatment arms (Table 1).

3.3. Failures, Revision Surgery, and Mortality

The failure frequency at 2 years was similar in the Pinloc (14%; 23/169) and Hansson pin (16%; 25/156) groups Table 2). Revision surgery within 2 years was performed in 11% (18/169) of patients in the Pinloc group and in 10% (16/156) in the Hansson pin group (excluding implant extractions due to local pain) (Table 2). The type of failure and indication for surgery were similar in both groups. An additional 11% (19/169) of patients in the Pinloc group compared with 9% (14/156) of patients in the Hansson pin group had implant removal due to local pain. Two-year mortality was 25% (43/169) and 22% (34/156) in the Pinloc and Hanson pins groups, respectively.

3.4. Timed Up and Go Test

In both groups, about 2/3 (109 vs. 103) were able to perform the TUG at the first follow-up and about half at 12 months (89 vs. 83). At 3 months, the median time was 14 seconds in the Pinloc group compared with 15 seconds in the Hansson pin group. At 12 months, the times were 12 and 11 seconds, respectively (see Appendix Table 1, http://links.lww.com/OTAI/A78). When reoperations were excluded, still no statistically significant differences were found.

3.5. Patient-Reported Outcome Measures

Not all patients included in the study were able to perform complete PROMs. In addition, the number of respondents dropped at both follow-ups because of death and inability to fill out the forms but was around 70% at 12 months (see appendices 2 and 3).

Before the fractures, patients in both treatment groups had similar results in EQ-5D, VAS, and WOMAC, including all subscores. The results did not statistically differ between the groups at 3 or 12 months postoperatively (see Appendix Tables 2 and 3, http://links.lww.com/OTAI/A79, http://links.lww.com/OTAI/A80). Even after excluding patients who had had revision surgery from the analysis, no statistically significant differences were found between the Pinloc and Hansson pin groups.

3.6. Displaced Fractures

One hundred and forty-two patients were randomized, and 114 were included in the analysis. Twenty-eight were lost to follow-up because they moved away or declined further participation in the study (Fig. 1). Demographics including age, BMI, dementia, and smoking were similar in the 2 treatment groups. Among younger

TABLE 1

Patient Demographics

	Nondisplaced		Displaced Age 50–69 years		Age 70 years or older	
	Pinloc (n = 169)	Hansson Pins (n = 156)	Pinloc (n = 39)	Hansson Pins (n = 36)	Pinloc (n = 21)	Hansson Pins (n = 18)
Women/men	129/40	115/41	19/20	14/22	15/6	11/7
Age, median (IQR)	80 (73–86)	80 (71–87)	59 (56–64)	62 (58–65)	84 (78–87)	82 (77–88)
BMI, mean (SD)	24 (4)	23 (4)	25 (4)	26 (5)	25 (4)	25 (4)
Dementia	31	19	0	1	7	5
Smoking	21	21	11	13	2	0

IQR, interquartile range; SD, standard deviation.

patients, the Hansson pin group had a higher proportion of men (Table 1).

3.7. Failures, Revision Surgery, and Mortality

The 2-year failure rate was similar in both groups; 40% (24/60) in the Pinloc group and 37% (20/54) in the Hansson pin group. In a subgroup analysis of the predetermined age groups 50–69 and 70 years or older, the failure rates were also similar (Table 3).

Revision surgery was performed in 33% (20/60) in the Pinloc group and 31% (17/54) in the Hansson group. As with failures, similar results were found in the analysis of the 2 age subgroups (Table 3). Indications for revision surgery were similar between the groups. Mortality was 18% (11/60) and 17% (9/54), respectively; however, for the subgroup of patients older than 70 at the time of fracture, mortality was 29% (6/21) and 44% (8/18).

3.8. Patient-Reported Outcome Measures and Timed Up and Go Test

Not all patients included in the study were able to complete PROMs and perform the TUG test. The number of respondents dropped at both follow-ups because of death or inability to perform the tests. The results are presented separately for the 2 age categories because they are expected to have very different function. Participation remained reasonably high at around 75% at 12 months for the younger patients (50–69 years) but was as low as 30% for patients aged 70 years or older.

For the younger age group (50–69), no clinically significant differences were found for EQ-5D, WOMAC, or TUG between treatment groups at 3 and 12 months (see Appendix Tables 4–6, http://links.lww.com/OTAI/A81, http://links.lww.com/OTAI/A82, http://links.lww.com/OTAI/A83). Excluding those who had undergone revision surgery, almost half of the responding patients, we could not find any significant differences.

Among patients aged 70 or older, both treatment groups were small and only about a third of included patients had completed questionnaires that were possible to analyze at 12 months. The Hansson pin group had clinically and statistically significantly better VAS scores at 3 months (73 vs. 60, $P = 0.01$). Most patients having had revision surgery did not complete PROMs, making a separate analysis unfeasible. TUG was lower among Hansson pins patients at 12 months (median 11 vs. 19 seconds, $P = 0.03$). However, the responders were only 5 and 8 patients in the 2 groups.

TABLE 2

Failures and Reoperations Among Patients With Nondisplaced Fractures

	Pinloc (n = 169)	Hansson Pins (n = 156)
Failures (total)	23	25
Infection	1	1
Early displacement/nonunion	9	16
Symptomatic avascular necrosis	10	7
New fracture	3	1
Reoperations (total)	37	30
Arthroplasty	13	14
Reosteosynthesis	3	1
Girdlestone	2	1
Extraction	19	14

No statistically significant differences were found between groups.

4. Discussion

In this multicenter, randomized controlled trial, comparing Pinloc with Hansson pins for the treatment of both displaced and nondisplaced FNFs, there was no significant difference in the fracture failure rate between the treatment groups, within the first 2 years after surgery. There were also no clinically significant differences in secondary outcome parameters. Mortality, reoperations, patient-reported outcomes measures (EQ-5D and WOMAC), and physical function, assessed with a TUG test, were similar between groups. The only statistically significant difference found was a better VAS score among elderly patients (70 years or older) with displaced fractures treated with Hansson pins at 3-month follow-up. EQ-5D score at 3 months contradicted this finding, and the difference was not reflected in the results of the functional test. When doing multiple comparisons, false-positive results are likely to be encountered. Therefore, our conclusion is that this finding likely does not represent a meaningful difference.

The failure and reoperation rates in the 2 treatment groups are well aligned with data from previous studies, using a multitude of implants.[5,7,19] For example, the failure rate of internal fixation with any of the 2 implants was 28% in patients older than 70 with displaced fractures, supporting the recommendation for arthroplasty as the primary treatment modality in this group. There were no statistical differences between different modes of failure between the groups.

In this study, we found a relatively high rate of hardware removal at 11% for Pinloc and 9% for Hansson pins. This might be explained by the extra attention to lateral pain that the study protocol provided. We could not detect a difference between the implants. However, in a subanalysis from the FAITH[7] study, 23% of healed fractures had implant removal and in a registry

TABLE 3

Failures and Reoperations Among Patients With Displaced Fractures

	Age 50–69 years		Age 70 years or older		All	
	Pinloc (n = 39)	Hansson Pins (n = 36)	Pinloc (n = 21)	Hansson Pins (n = 18)	Pinloc (n = 60)	Hansson Pins (n = 54)
Failures (total)	17	16	7	4	24	20
Infection	0	0	0	0	0	0
Early displacement/Nonunion	9	11	4	3	13	14
Symptomatic avascular necrosis	8	4	3	1	11	5
New fracture	0	1	0	0	0	1
Reoperations (total)	21	21	7	3	28	24
Arthroplasty	16	12	3	3	19	15
Reosteosynthesis	0	1	0	0	0	1
Girdlestone	0	1	1	0	1	1
Extraction	5	7	3	0	8	7

No statistically significant differences were found between groups.

study from Finland[21]; between 1997 and 2016, 11.3% of cannulated screws for femoral neck fractures were removed (not including revision to THA). These findings are similar to ours.

There were no statistically significant differences in the TUG test between the 2 groups at 3 or 12 months, except for in the small subgroup of displaced fractures 70 years and older. In a meta study, Bohannon[22] concluded that TUG results of 8-9-11 seconds in mean were normal for healthy 60–70, 70–80, and 80–99-year-olds, respectively. The median age in our study was 80 years, and because the subjects had sustained a hip fracture, they probably had more health issues than the average population at that age. However, at 12 months, the patients able to perform the TUG had median results of 12 and 11 seconds in the 2 groups of nondisplaced fractures. The mean results were 16 and 18, when no outliers were excluded. Based on these numbers, we think patients in these selected groups had recovered close to prefracture mobility.

Furthermore, analyses were made where reoperated patients were excluded. An implant may not be superior at avoiding failures and reoperations, but it may still give a subjectively better outcome among those not having a failure. However, no difference was found between the 2 groups, indicating that one implant was not superior to the other neither during the healing process nor after the fracture had healed.

4.1. Strengths

This study is a relatively large randomized study in a population of patients that is notoriously difficult to follow over time. The randomization was performed after reduction of the fracture to eliminate confounding because of differences in the quality of fracture reduction between groups. Previous studies on displaced FNFs suggest that the quality of reduction predicts outcome more than the implant used.[20,23]

The multicenter approach and the fact that many different surgeons were involved in the surgical treatment contribute to the pragmatic approach of the study and potentially increase external validity.

A concise panel of outcome parameters was used. The primary outcome parameter was the rate of failure because it is more comprehensive than reoperation rates. To evaluate health-related quality of life, we used EQ-5D with 5 dimensions reflecting mobility, self-care, common activities, pain, and anxiety/depression. We also included a hip-specific score, WOMAC, to evaluate hip function. Both these PROMs have been used in several previous hip fracture studies,[24–26] but, to our knowledge, this is the first large prospective randomized study recording PROMs after internal fixation of nondisplaced FNFs. In addition, we included the TUG test which is a functional test of mobility in a real-life setting.

4.2. Weaknesses

The most significant weakness of the study is related to the number of patients who were available for analysis. First, we estimate that roughly 500 patients with FNFs were treated with internal fixation without being screened for inclusion. This was mainly due to variability in the acceptance of the Hansson pins and Pinloc implants among treating surgeons at the different study sites and should therefore not introduce selection bias. Second, the expected difference in outcome between subgroups (nondisplaced vs. displaced) necessitates analysis at the subgroup level, decreasing the number in each analysis. Third, owing to the fragility of many patients, we had a significant degree of loss to follow-up. This was most pronounced for the PROMS and TUG because these parameters required visit at the clinic. According to prestudy power analysis, at least 128 patients with displaced fractures would be required to reach a power of 80%. Although 142 displaced fractures were randomized, only 114 were possible to analyze at 2 years.

The pragmatic aspect of the multicenter study comes with the drawback that the procedure was distributed among many surgeons. A new implant has a learning curve. Although Pinloc shares many features with Hansson pins and commonly used locking plates, it was new to most surgeons in the study. An attempt was made to overcome this inexperience with simulator training before initiation of the study. Even so, the learning curve may have skewed the result in favor of Hansson pins which all surgeons had extensive experience with.

5. Conclusion

We found no clinically important differences between Pinloc and Hansson pins in the treatment for displaced nor nondisplaced fractures of the femoral neck. The only statistically significant difference was found in a small subgroup among secondary outcomes, which may be considered a consequence of multiple comparisons.

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